



May 10, 2021

«Company_Name»
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«city», «state» «zip»

Re: MD Labs 2021 Referring Provider Annual Notice

We hope you are having a safe and prosperous 2021 and thank you for continuing to choose MD Labs as your laboratory services provider. We are committed to providing the highest level of service for your practice and your patients and work hard every day to earn your trust.

As part of our ongoing compliance program, we are providing you with the enclosed *Referring Provider Annual Notice* that shares our most current policies and related forms. The Office of the Inspector General (OIG) recommends laboratories share this information as part of a compliance program annually. MD Labs strives for a gold standard compliance program, and we endeavor to provide each referring provider this notification each calendar year going forward.

Included with this letter are the following policies, forms, and documents:

- MD Labs 2021 Oral Fluid and Urine Drug Testing
- MD Labs 2021 Additional Toxicology Testing Request
- MD Labs 2021 Pharmacogenetics Testing
- MD Labs 2021 Urinary Tract Infection (UTI) Testing
- MD Labs 2021 Screening for Sexually Transmitted Infections (STI)
- MD Labs 2021 Women's Health Testing
- MD Labs 2021 Wound Testing
- MD Labs 2021 Respiratory Testing
- MD Labs 2021 Gastrointestinal (GI) Testing
- MD Labs 2021 Nail Fungal Testing
- MD Labs 2021 Payers Requiring Signed Requisition & Medical Records
- MD Labs 2021 Self-Pay Pricing Mar 2021
- MD Labs 2021 Financial Assistance Disclosure Application
- MD Labs 2021 Certification of Determination of Financial Need & Request to Offer Patient Discount
- MD Labs 2021 Patient Election to Self-Pay for Services
- MD Labs 2021 Revocation of Patient Election to Self-Pay for Services
- Are You in Compliance with CMS Rules (Noridian MAC)?
- Advance Beneficiary Notice of Noncoverage (ABN) Instructions
- ABN Form and Instructions (English)
- ABN Form and Instructions (Spanish)
- MD Labs 2021 Request for Additional Information Form and Instructions
- National, LCD and CMS Guidelines

Would you please obtain all your providers' signatures on the flagged form and return it to us via scanned email, fax, or US Post? Provider signatures acknowledge receipt of this required documentation and would be appreciated at your earliest convenience.



Email to BillingQuestions@MDLabs.com, or

FAX to **775-737-9133**, Attn: Compliance, or

Mail to MD Labs, 10715 Double R Blvd, Suite 102, Reno, NV 89521 Attn: Compliance

You can find an educational video that outlines this process on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Compliance Resources**.

Should you have any questions about the forms or this request, please contact your MD Labs representative or reach out to the lab directly at **775-391-5221**.

Thank you,
MD Labs



To: All Clients
From: Compliance Department
Re: MD Labs 2021 Referring Provider Annual Notice
Date: May 2021

MD Labs is providing this notice in accordance with the recommendation made by the Office of Inspector General (OIG) as part of our Compliance Program. Periodically, MD Labs will advise its provider clients about program changes and information related to federally funded health care programs.

When ordering tests for which Medicare reimbursement will be sought, the following policies apply:

Orders are only accepted by Licensed Physicians and Non-Physician Practitioners.

A clinical laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests. If your license has been revoked or suspended, please immediately notify MD Labs. As of 2014, Medicare requires registration of all ordering providers to the Center for Medicare and Medicaid Services Provider Enrollment, Chain, and Ownership System (PECOS). More information on PECOS and how to enroll in the system may be viewed at <https://pecos.cms.hhs.gov/providers/index.html>. You can find a complete list of the links mentioned in this notice on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources**. Click on the option titled, **Other Important Links**.

Excluded Clients

MD Labs will not accept orders for tests from any individuals or entities debarred, excluded, or otherwise declared ineligible from participation in federal or state-funded health care programs or that have lost their licenses to provide health care services.

MD Labs will continually review the HHS/OIG *List of Excluded Individuals or Entities* database to ensure no existing clients are debarred, excluded, or otherwise declared ineligible from participation in federal or state-funded health care programs. MD Labs will monitor appropriate sources to ascertain whether a client have lost their licenses to provide health care services.

Any provider who appears on any debarred, excluded, or ineligible list will immediately receive notification of such. MD Labs cannot accept orders from any provider during a sanctioned period. MD Labs will resume accepting orders with reasonable proof that the provider has been reinstated in federal or state-funded health care programs or has had their license reinstated.

New Ordering Providers

If you should add new Ordering Providers to your practice, please reach out to your MD Labs account representative so that MD Labs can add your new medical staff member to your account.

Medicare Medical Necessity Policy

Tests that are medically necessary for the diagnosis or treatment of a Medicare patient are covered and are reimbursable. However, we cannot guarantee reimbursement from Medicare.

The OIG takes the position that physicians or other individuals authorized by law to order laboratory tests, who knowingly cause a false claim submission to any federally funded program, may be subject to sanctions or remedies available under civil, criminal and administrative law, such as the False Claims Act.

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Fast-Facts/False-Claims>.



You can find a complete list of the links mentioned in this notice on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources**. Click on the option titled, **Other Important Links**.

Diagnosis Coded to Highest Level of Specificity

Section 4317 of the Balanced Budget Act of 1997 requires the physician or authorized ordering party to submit diagnosis information on the laboratory order for submission of a Medicare claim. The diagnosis information supplied needs to be coded to the highest level of specificity and accurately describe the patient's condition on the date of service, as documented in the patient's medical record. MD Labs will contact providers for all requisitions that do not include this required information, this communication may occur via telephone call, email, or fax.

Ordering Physician/Practitioner Signature Requirements

While the physician's signature is not required when initially ordered for clinical diagnostic tests, upon review by Medicare contractors, there must be evidence to support the physician's intent to order the tests performed and documentation of medical necessity in the patient's medical record. However, it is quickly becoming a requirement of other commercial insurance carriers. MD Labs has experienced an increase in requests for signed requisitions and medical records documentation from the following commercial carriers (see attached payer list). In order to prevent unnecessary delays in billing the added work and financial burden to your office and/or patients, MD Labs strongly encourages you to sign the MD Labs requisition form.

CMS provides signature requirements guidance via CMS Change Request CR9225, CR9332:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03pdf.pdf>.

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Are you in Compliance with CMS Rules? (Noridian CMS)

For any services to be covered by Medicare, the patient's medical record must contain sufficient documentation to support the need. Such documentation should include the patient's diagnosis and other pertinent information, the duration of the patient's medical condition, clinical course (worsening or improving) prognosis, among others.

Your cooperation is a legal requirement as outlined in the Social Security Act. The law governing Medicare Section 1842(p)(4) of the Act mandates that:

In case of an item or service...ordered by a physician or practitioner...but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic and or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time the item or service is ordered by the physician or practitioner. (Attached is the letter from Noridian Healthcare Solutions, MD Labs Medicare Part B Intermediary)

Medical Records Chart Notes

Most payer requests around laboratory services are related to insufficient documentation. When documentation is insufficient, something is missing from the lab requisition or the medical records, such



as signatures, sufficient chart notes, documented intent to order. Insufficient documentation may lead to denied claims, additional labor for your office, denied payments and increased patient bills.

An *order* is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The medical record and/or the request itself must clearly document the physician's intent to have the diagnostic test performed.

CMS recommends utilizing the following when charting in a patient medical record:

- Who: Who is the Patient?
- What: What is the reason for the visit?
- When: When was the Patient seen (date & time of visit)?
- Why: Why is the patient being seen?
- How: How were the symptoms treated?

CMS has a short podcast: *Provider Minute: The Importance of Proper Documentation* – for your convenience, MD Labs has a link to this podcast on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources**. Click on the option titled, **Video – Proper Patient Documentation**.

2021 Medicare Clinical Diagnostic Laboratory Tests Payment System

Effective January 1, 2018, the Clinical Lab Fee Schedule (CLFS) reimbursement rates were revised to be based on the weighted median private payer rates as required by the Protecting Access to Medicare Act (PAMA) of 2014. Co-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule. Also, Medicaid reimbursement will be equal to, or lesser than Medicare reimbursement. The 2021 Medicare Clinical Laboratory Fee schedule may be viewed and downloaded at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files>.

You can find a complete list of the links mentioned in this notice on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources**. Click on the option titled, **Other Important Links**.

The Centers for Medicare and Medicaid Services has authorized Noridian, LLC, Nevada Medicare Part B carrier, to develop Local Coverage Determinations (LCD). These guidelines may supplement or be in addition to the National Coverage Determinations and give direction for medical necessity on selected tests. All laboratory LCDs are available at <https://med.noridianmedicare.com/web/jeb/policies>. You can find a complete list of the links mentioned in this notice on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources**. Click on the option titled, **Other Important Links**.

Advance Beneficiary Notice of Noncoverage (ABN)

Medicare does not cover all laboratory services. An Advance Beneficiary Notice of Noncoverage (ABN) is one of the most critical Medicare forms you can utilize. Medicare states it must be made available to the patient when Medicare does not consider an item or service reasonable and necessary according to the patient's diagnosis or Medicare Policy.



Examples of everyday situations where an ABN is needed. Please include when the test ordered:

- Is considered experimental, investigational, or research only.
- Is not indicated for the diagnosis or treatment of the patient.
- Exceeds the frequency of services allowed for a specified period for the corresponding diagnosis.

A new ABN form needs to be signed for each encounter. The ABN is proof that the patient received notification that Medicare payment is expected to be denied for their laboratory services. As an informed consumer, the patient can then decide whether to accept the laboratory services as an out-of-pocket expense or through other insurance if available.

MD Labs ABN Policy

MD Labs will not bill Medicare patients for laboratory testing that Medicare has determined is not “reasonable and necessary” unless the patient has signed an ABN before collecting the specimen for the laboratory testing being ordered. ABN information and forms are available on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources** to download an ABN form. Please find additional information about ABNs at:

<https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN>.

You can find a complete list of the links mentioned in this notice on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources**. Click on the option titled, **Other Important Links**.

Billing Information

MD Labs requires the following information to enable our Billing Department to bill Medicare, Medicaid, or other commercial insurance. This information can either be provided on the MD Labs requisition form or included on enclosures to the requisition form.

- The patient’s full name, date of birth, gender, and address. A copy of the patient’s face sheet or lab requisition order with this information can be provided instead of including the information on the Requisition form.
- Insurance information, including the insurer’s name, address, and phone number. A copy of the lab requisition order with this information, or a copy of the insurance card (front and back), can be provided instead of including the information on the Requisition form.
- Ordering provider’s name and NPI number.
- Valid ICD-10-CM diagnosis code(s) defined to the highest level of specificity, for each test ordered to confirm medical necessity.
- Valid ABN, when mandated by Medicare NCD/LCD policy.

Billing Information SARS-CoV-2 (COVID-19)

MD Labs has developed a multiplex RT-PCR test that quickly and accurately identifies a COVID-19 infection. Our laboratory operates under the quality standards of the FDA, CAP, and CLIA.



The following patient demographics are required and must be submitted with each specimen:

- Patient Name
- Date of Birth
- Street Address (cannot be PO Box)
- County
- Phone Number
- Race and/or ethnicity

The ordering provider must also agree to promptly comply with any requests for medical documentation required to adjudicate of MD Labs claims.

Compliance with *Federal Beneficiary Inducement Statute, Anti-Kickback Statute, Stark Law and EKRA*

MD Labs' policy is to fully comply with the *Medicare Beneficiary Inducement Statute, Anti-Kickback Statute (AKS), Stark Law, and Eliminating Kickback in Recovery Act (EKRA)*. MD Labs prohibits its employees from offering or providing remuneration to clients or patients to induce or influence a physician, non-physician practitioners, and other types of clients to refer that patient's testing to MD Labs.

The term *remuneration* includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include— (A) the waiver of coinsurance and deductible amounts by a person, if (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the provider does not routinely waive coinsurance or deductible amounts; and (iii) the provider (a) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or (b) fails to collect coinsurance or deductible amounts after making reasonable collection effort. Please review the following web pages for more information:

<https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>

<https://www.congress.gov/bill/115th-congress/senate-bill/3254/text>

<https://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf>

You can find a complete list of the links mentioned in this notice on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources**. Click on the option titled, **Other Important Links**.

Reflex Testing

MD Labs offers client-specific reflex testing for individual patient specimens when requested. An example of reflex testing would be D- or L- methamphetamine confirmatory testing when any patient's initial screen for methamphetamine was positive or reflexing to a respiratory pathogen panel when a patient's COVID-19 test results are negative. Reflex testing is an option in each requisitioning format.

Verbal Orders & Add-on Testing

To verbally request additional tests to be added to an existing order, please call MD Labs Customer Service at **775-499-5150** and an MD Labs representative will verify the specimen is available and adequate for testing. You will then be instructed to fax a new order for the tests you add to our Customer Service Department at **775-737-9133**. This additional order needs to be maintained in the patient's medical record. Testing will not be performed until the signed confirmation or a properly completed MD Labs requisition form is returned to the laboratory.



Test Cancellations

MD Labs will honor test cancellation requests submitted before test completion. If the cancellation request is received after the specimen has been analyzed, and the result has been produced, the request cannot be honored, and the usual test charge will be assessed.

Contracted Payers

MD Labs is a Medicare, Medicaid, and Military certified lab that provides and participates as an in-network facility with Medicare Advantage programs and managed Medicaid programs. We are in acceptance of national, regional, and state commercial managed care organizations, federal/state employee *Medi-Gap*, and employer/TPA programs.

Fee Schedules

Our list price fee schedule, which is the same as the Medicare fee schedule, and our self-pay fee schedule for uninsured or under-insured patients are attached for your reference. Prices are subject to change without notice.

Self-Pay Patient Billing Policy

Insured patients are billed deductibles, co-insurance and co-payments as required by their insurance provider. MD Labs reserves the right to use resources available to search for active insurance if the information is not provided or if the order is marked "Uninsured" or "Patient Does Not Have Insurance Coverage."

In 2013, the Department of Health and Human Services issued updates to HIPAA privacy regulations, giving patients more control over who has access to their personal health information (PHI), including their own insurance companies. Under HIPAA, patients may opt-out of using their insurance benefits to prevent reporting this service to their insurance carrier. Additionally, on Feb. 18, 2010, the HITECH Act regulated that a health care provider is required to honor a patient's request to restrict disclosure of PHI to a health plan for purposes other than carrying out treatment (specifically, payment or health care operations) if the patient pays the health care provider out of pocket in full¹. For example, if a patient does not wish to use their health insurance, they can request that the insurance not be billed.

MD Labs offers a patient self-pay option for uninsured, underinsured, or patients that wish to waive insurance benefits. Patients seeking testing services who do not wish to use their insurance coverage must sign a patient *Election to Self-Pay*. By signing the *Election to Self-Pay*, patients are stating that they have chosen to opt-out of their insurance. By doing so, MD Labs will not be filing a claim with their insurance company.

MD Labs must be informed at the time of ordering if the patient is choosing this option, and the patient's insurance information must be provided. The patient will be billed at the MD Labs self-pay rate for the services performed. If payment for such service is not received within 60 days, MD Labs will bill the patient's insurance to secure reimbursement. If the patient has no insurance, MD Labs will bill the patient at the MD Labs self-pay rate. MD Labs reserves the right to revoke the *Election to Self-Pay* at any time.

Should patients change their minds and would like MD Labs to begin filing their insurance - once the deductible is met, for example - they can sign the *Revocation of Election to Self-Pay* form. Both forms are available on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the screen, then click **Billing Resources** to download either of the forms.

¹ Reference: [Section 13405 of Subtitle D of the HITECH Act (42 USC 17935)]



Financial Assistance Program

Only at a client's request and when the client offers a similar discount or waiver of their own charges or fees will MD Labs agree to provide testing for that client's needy patients at a reduced cost. The MD Labs Compliance Officer reviews and monitors all requests for financial assistance. Financial assistance applications and information are available on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources** to review the *Financial Assistance Disclosure Application (FADA)* and the *Certificate of Determination of Financial Need*.

Requests for Additional Information

MD Labs will provide *Requests for Additional Information* on a weekly basis as needed, and the missing or incomplete information will be clearly identified on the MD Labs *Request for Additional Information Form*. Our form is an editable pdf document, so please type the information directly onto the report. Diagnosis Codes must be coded to the highest level of specificity for the laboratory test(s) ordered and require the Ordering Practitioner's signature.

Send completed requests to:

- Email to BillingQuestions@mdlabs.com, or
- FAX to **775-737-9133**, Attn: Billing, or
- Mail to: MD Labs 10715 Double R Blvd, Ste. 102, Reno, NV 89521 Attn: Billing

Should you have any questions or concerns please call our Billing Department at **775-499-5150**.

Customer Service

Customer service representatives are available 6am to 6pm PST, seven days a week at **775-499-5150**.

Included with this letter are the following policies, forms, and documents:

- MD Labs 2021 Oral Fluid and Urine Drug Testing
- MD Labs 2021 Additional Toxicology Testing Request
- MD Labs 2021 Pharmacogenetics Testing
- MD Labs 2021 Urinary Tract Infection (UTI) Testing
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- MD Labs 2021 Wound Testing
- MD Labs 2021 Respiratory Testing
- MD Labs 2021 Gastrointestinal (GI) Testing
- MD Labs 2021 Nail Fungal Testing
- MD Labs 2021 Payers Requiring Signed Requisition & Medical Records
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- ABN Form and Instructions (English)
- ABN Form and Instructions (Spanish)



- MD Labs 2021 Request for Additional Information Form and Instructions
- National, LCD and CMS Guidelines

Attached to this letter is a set of supporting documents from MD Labs, if you would like additional copies, please notify your MD Labs account representative.

Please take a minute to review this information with your appropriate staff. We value your staff and patients and appreciate the opportunity to serve your laboratory needs in conjunction with these initiatives. A copy of this 2021 Referring Provider Annual Notice is located on our website. Please go to **MDLabs.com**, click on the **Resources** tab at the top of the page, then click **Billing Resources** to review the additional documents and the *Provider Acknowledgement Letter*.

If you have further questions regarding this information, please contact your MD Labs account representative.

Kind Regards,
MD Labs